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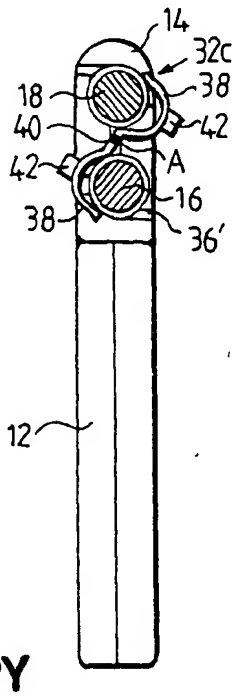
(54) An appliance for fixing one or more electrode leads in a heart stimulator

(57) The invention relates to an appliance for fastening one or more electrode leads (16,18) in a connector unit (14) of an implantable medical device, for example a heart stimulator (10). The fastening appliance is made of a wire- or strip-shaped resilient locking member (32c), which is arranged to be inserted and fixed in a cavity (36') in a connector unit (14) and which is shaped to clampingly engage diametrically opposed circumferential parts of the casing of each electrode lead (16,18).

Fig.5



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Description

The present invention relates to an apparatus for fastening at least one electrode lead in an insertion hole in a connector unit for an implantable medical device, e. g. a heart stimulator, such as a pacemaker or defibrillator.

It is important during the connection of the proximal end of one or more electrode leads or conductors to the connector of a heart stimulator that each lead end is axially and radially securely held in the connector in order to ensure a good electrical contact and in order to prevent detaching of the electrode lead end from the connector.

In a prior art electrode lead fixing means of a simpler type, the electrode end was inserted into a hole in the connector which was adapted to the diameter of the end of the electrode, whereby the end of the electrode was radially held fast in the hole. The axial locking or fastening of the end of the lead is achieved with the aid of a set screw, which is screwed into a respective transverse screw hole in order to radially press a male plug part on the end of the electrode lead from one side against an opposing wall of a socket thereby to achieve a clamping of the end of the lead and thus also an axial fastening of it in the hole. The use of screws requires tools for the assembly and entails a requirement for precise instructions and a precise tightening force on the screw.

US-A-4 848 346 discloses a pacemaker connector system which eliminates problems associated with set screw systems. In this device the connector block firmly holds two circular springs which can be expanded to allow insertion of the heart lead by depressing a straight end portion of the spring which protrudes from the outer surface of the connector block. However, such protruding end portions may cause unintentional actuation of the springs and inadvertent release of the heart lead.

It has also been suggested to use a wedge element (US-A-4 860 750) in order to fix the ends of the electrode conductors in the connector of the heart stimulator. Such a wedge element is insertable into a complementary channel which is orientated transversally and tangentially relative to the hole into which the electrode lead end is inserted, and has a cam profile with a concave seating surface in order to clamp the lead end through the lead casing when the wedge element is inserted. In this way the wedge element firmly holds the electrode lead in the hole from one side of the hole by means of elastic deformation of the lead end casing, which normally is made of a layer of silicon. With this wedge-shaped embodiment of the locking or fixing element the fastening of the ends of the electrode leads is achieved by means of a single-sided, asymmetric type of fixing element which cannot guarantee a constant wedging force within the tolerance range for electrode leads.

EP-A2-0 590 756 describes a fixing arrangement for an elec-trode lead in a connector of a heart stimulator. The fixing means is formed of a spring plate with opposing resilient gripping means cast in a connector, which is intended to cooperate with the contact pin on the lead and simultaneously prevent the end of the electrode lead being pulled out of the connector, whereby the retention force on the clamp increases when a withdrawing force is exerted on the electrode lead. The engagement of the gripping means on the contact pin of the lead end can be removed when a force is exerted on opposing, projecting side tabs on the spring plate.

An object of the present invention is to propose an improved and simplified fixing means which can provide a symmetric clamping of the end of the electrode lead effecting on opposing sides with a constant force within the tolerance range for the lead and which cannot be released if a clamping pressure is exerted upon the connector.

For this purpose the appliance of the present invention comprises a resilient locking member insertable into a slot in said connector unit, said slot being formed to hold said locking member in a plane substantially normal to a longitudinal axis of the bore, said locking member being adapted, upon insertion thereof into the slot, to straddle and resiliently snap over an insulating cover of the electrode lead so as to firmly hold diametrically opposite portions thereof.

In a suitable embodiment of the fixing means according to the invention for fixing of two or more electrode leads arranged in a row the resilient locking member is shaped to be successively pushed over the casings of the leads along a path which connects the central axes of the leads with alternating inward and outward springing of two opposing, preferably wave-shaped side branches of the resilient member. Such an embodiment provides a very simple mounting of the locking element as well as clamping the lead ends with a constant force from two opposing sides.

In another suitable embodiment of the fixing means according to the invention the resilient member is shaped so as to snapfasten over the casing of the electrode lead in a direction which is essentially transverse to a line which connects the central axes of adjacent leads. In this way the electrode lead ends can be clamped through a successive pushing of locking sections of the resilient locking member over the lead ends from the side. Such an embodiment makes it also possible to fasten three or even more electrode ends in a connector where the insertion holes for the respective lead ends do not have to lie in a straight line.

In yet a further embodiment of the fixing means according to the invention for fixing two electrode leads, the resilient element is S-shaped with two arcuate portions which open in opposing directions and which are joined by a web part, whereby the resilient member is rotatable about a transverse axis which is essentially parallel with the longitudinal axis of the electrode lead in the web part, in a cavity of the connector, from a passive position to a lead-clamping locking position, preferably inset in the connector. The resilient locking mem-

ber is placed in its cavity before the ends of the electrode leads are pushed into their respective connection holes, following which the resilient member is rotated to the locking position by simply pressing each of the arcuate ends in opposing directions.

In a further embodiment for fixing of a single electrode lead the resilient locking member has an arcuate part, shaped in order to be able to clamp against diametrically opposing parts of an insulating casing on the electrode lead and rotatable in a cavity in the connector about an axis which is essentially parallel with the longitudinal axis of the electrode lead, from a passive position to a lead-clamping locking position, preferably inset in the connector.

The invention will be described in more detail below with reference to the drawings, in which:

Figure 1 schematically shows a side view of a pacemaker with an upper electrical connector unit for two bipolar electrode leads, the connecting ends of which being fixed by means of a fixing appliance according to the invention;

Figure 2 is a schematic end view of the connector unit and a resilient locking member according to a first embodiment of the invention, before and after mounting;

Figure 3 is a view corresponding to Fig 2 but showing a second embodiment of the resilient locking member according to the invention, before and after mounting;

Figure 4 is a view similar to Figs 2 and 3 but showing a third conceivable embodiment of the resilient locking member according to the invention, before and after mounting;

Figure 5 is an end view of a pacemaker in Fig 1 and shows a fourth embodiment of the resilient locking member according to the invention, in a position before fixing of the lead ends;

Figure 6 is a view similar to Fig 5 but showing the resilient locking member in the active locking position in the connector;

Figure 7 shows a fifth embodiment of a resilient locking member according to the invention for mounting of a single electrode lead in a connector;

Figure 8 is an end view of the resilient locking member in Fig 7 in a position before fixing of the lead end; and

Figure 9 is a view similar to Fig 8 but showing the resilient locking member in the active locking position in the connector.

Figure 1 shows an implantable pacemaker with reference 10, which comprises a casing 12, which amongst others encloses an electronic unit (not shown) with a pulse generator, and a connector 14 in order to connect the electronic unit with, in this case, two proximal ends of bipolar electrical conductors 16,18, or so-called electrode leads, which are to be inserted via a peripheral vein and led via the upper carotid vein (vena cava superior) to the right side of the heart, where the electrodes at the distal lead end will come into contact with the heart muscle at a desired location.

There are two parallel blind holes 20,22 in the connector 14, which contain a respective contact element 24,26 for connection and contact with corresponding contact elements on the ends of the electrode leads 16,18, when these are inserted in the respective blind holes 20,22.

In order to attach the lead ends in the connector 14 it is suggested according to the present invention to use a simple resilient locking member, which could encompass parts of diametrically opposing circumferential halves of the casing of the lead ends and clamp them with a constant force.

Figure 2 shows a first embodiment of a simple resilient locking member 32 according to the invention for the simultaneous fastening of two electrode lead ends 16,18. The resilient member 32 can be formed from a wire or a narrow strip of material suitable for the purpose, e.g. titanium, stainless spring steel or a plastic material, and has two essentially wave-shaped side branches 34a,34b and a web part 34c joining them. The configuration of the side branches 34a,34b and the web part 34c are therefore such that the casing of the lead ends 16,18 is subjected to symmetrical pressure forces directed towards each other, which are constant within the tolerance range for the casing of the lead ends 16,18, when the resilient locking member 32 is mounted on them. In the embodiment in Figure 2 the resilient locking member 32 is attached on the lead ends 16,18 inserted in the connector 14 by inserting in the direction of arrow P in a slot 36 in the connector 14, whereby the resilient member is pushed successively over the leads along a path which connects the central axes of the leads 16,18, with alternating springing in and out of the two opposing, wave-shaped side branches 34a,34b on the resilient member 32. The slot 36 is shaped and dimensioned so that the resilient member 32 is held axially fixed in it. In this way, in the mounted condition, the lead ends 16,18 are radially held in the connector 14 through a tight fit in their respective holes 20,22, and axially fixed by means of the resilient member 32, of which the branches 32a,32b are pressed in somewhat in opposing side portions of the elastic outer casing, normally made of silicon, of the electrode lead ends. In the active clamp-

ing position the resilient member 32 is enclosed within the outer contours of the connector 14, as shown in Figure 2.

Figure 3 shows a second embodiment of a resilient locking member 32a according to the invention for the simultaneous fastening of two electrode lead ends. Like the embodiment in Figure 1 the resilient member 32a in this embodiment is formed of a wire- or strip-shaped resilient material but has a wave-like configuration which permits pushing of the resilient member over the lead ends 16,18 in a lateral direction, essentially transverse to a line which connects the central axes of the leads, as is shown with arrow P' in Figure 3. In this way the resilient member is first snapped over one lead end and subsequently over the other end while being inserted in the slot 36. In the mounted position the resilient member 32a is enclosed within the outer contour of the connector 14, as shown in Figure 3, and presses into the opposing upper and lower portions of the elastic outer casing of the lead ends 16,18.

A third conceivable embodiment of a resilient member 32b according to the invention is shown in Figure 4, where the ends of three electrode leads 16,18,19, which do not have to lie in the same vertical plane of the connector 14, are to be fastened in the connector 14. In principle, this embodiment corresponds to an extension of or an addition to the resilient member 32a in Figure 3 with a further wave-shaped part. The snapping of the resilient member 32b over the lead ends occurs similarly in sequence in a slot 36 in the connector 14.

A fourth embodiment of a resilient member 32c according to the invention is shown in Figures 5 and 6, and consists of a wire or a strip element with two arcuate portions 38 facing in opposite directions and a straight web portion 40 connecting them. The resilient member 32c is inserted in a slot 36' in the connector 14 and is rotatable there about an imaginary transverse axis A in the web portion 40 from a passive position shown in Figure 5, in which the lead ends 16,18 can be inserted without any resistance into the contact position with the corresponding contact elements 24,26 in the connector 14 (Figure 1), to a lead end clamping position retracted in the connector as is shown more clearly in Figure 6. The arcuate parts 38 can be equipped with small pressing plates 42 in order to facilitate a manual locking of the resilient member 32c.

Figure 7 shows a connector 14 for a single electrode lead 17 with a locking resilient locking member 32d according to a fifth embodiment of the invention. The locking member 32d has an arcuate part which in similarity with the embodiment in Figures 5 and 6 can be rotated about an axis B between a position shown in Figure 8, in which the electrode lead end can be inserted into the insertion hole in the connector 14, and a fixing position according to Figure 9 partially surrounding an electrode lead end casing. A pressure plate 42 similar to the embodiment according to Figures 5 and 6 can be arranged on the arcuate part in order to facilitate the manual locking of the resilient member 32d.

Furthermore, the embodiments of the resilient member according to the invention do not require any tools for mounting of the resilient member.

Claims

1. An appliance for fixedly holding at least one electrode lead (16,18) in a respective insertion hole (20,22) in a connector unit (14) of an implantable medical device (10), **characterized by** a resilient locking member (32;32a;32b) insertable into a slot (36) in said connector unit (14), said slot (36) being formed to hold said locking member in a plane substantially normal to a longitudinal axis of the hole (20,22), said locking member being adapted, upon insertion thereof into the slot to straddle and resiliently snap over an insulating casing of the electrode lead so as to firmly hold diametric-ally opposite portions thereof.

2. An appliance according to Claim 1 for holding at least two or more electrode leads arranged in a line, **characterized in** that the resilient member (32) is shaped to be successively pushed over the casing of the electrode leads along a path (P) which connects the central axes of the leads (16,18), with alternate springing in and springing out of two opposing side branches (34a;34b) of the resilient member (32).

3. An appliance according to Claim 2, **characterized in** that the side branches (34a,34b) are essentially wave-shaped.

4. An appliance according to Claim 1 for fixedly holding two or more electrode leads, **characterized in** that the resilient member (32a;32b) is shaped so as to, with a snap-action, be pushed over the casing of the electrode leads in a direction (P') which is essentially transverse to a line which connects the central axes of the adjacent leads (16,18,19).

5. An appliance according to Claim 4, **characterized in** that the resilient member (32a;32b) has a wave-like configuration of adjacent sections with partially circular shapes, shaped to clampingly contact diametrically opposing circumferential parts of the respective leads (16,18).

6. An appliance according to any one of Claims 1-5, **characterized in** that the resilient member in the active clamping position lies enclosed within the outer contour of the connector unit (14).

7. An appliance for fixing of two electrode leads in insertion holes in a connector unit (14) of an electronic

unit (12) in an implantable medical device (10), **characterized in** that a wire- or strip-shaped resilient locking member (32c) has an S-shaped form with two arcuate parts (38) facing in opposite directions, which are joined by a web portion (40), whereby the resilient member is rotatable in a recess (36') in the connector unit (14) about a transverse axis (A) on the web portion (40), which is essentially parallel with the longitudinal axis of the electrode cables (16,18), from a passive position to a cable-clamping locking position preferably enclosed within the connector unit (14).

8. An appliance for fixing of an electrode lead (17) in an insertion hole in a connector unit (14) of an electronic unit in an implantable medical device, **characterized by** a wire- or strip-shaped resilient locking member (32d) with an arcuate part, shaped to clampingly engage diametrically opposed parts of an insulating casing of the electrode lead (17) and rotatable in a cavity in the connector unit (14) around an axis (B), which is essentially parallel with the longitudinal axis of the electrode lead (17), from a passive position to a lead-clamping locking position preferably enclosed within the connector unit (14).

9. An appliance according to any one of claims 1-8, **characterized in** that the resilient member (32;32a; 32b;32c;32d) has a thickness adapted to tightly fit in the cavity (36;36') in the connector unit (14).

10. An appliance according to claim 9, **characterized in** that the cavity has the shape of a slot (36;36').

11. An appliance according to any one of claims 1-10, **characterized in** that the resilient member (32;32a-32d) is made of titanium.

12. An appliance according to any one of claims 1-10, **characterized in** that the resilient member (32;32a-32d) is made of stainless steel.

13. An appliance according to any one of claims 1-10, **characterized in** that the resilient member (32;32a-32d) is made of plastic.

Fig.1

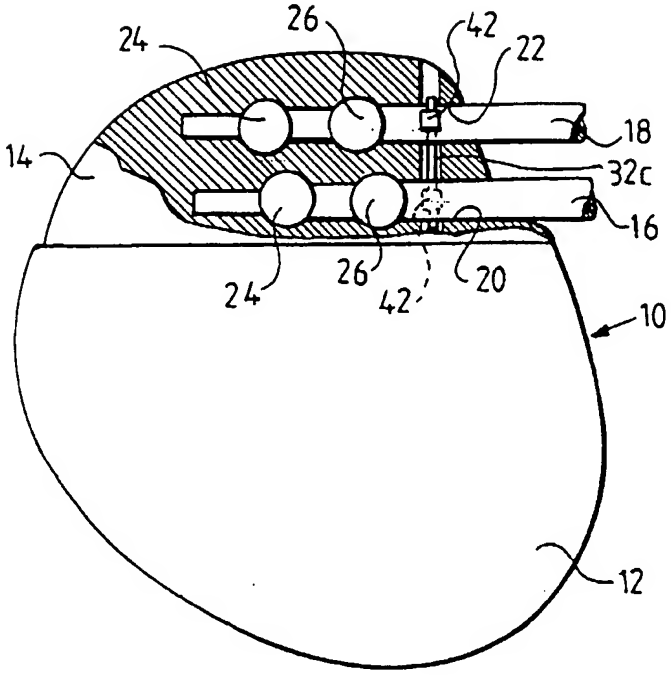


Fig.2

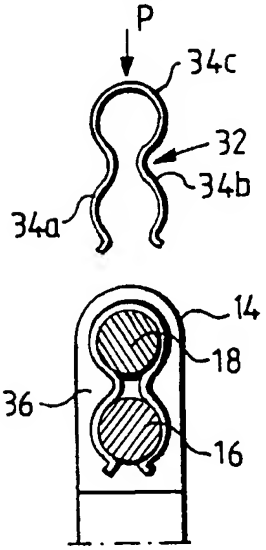


Fig.3

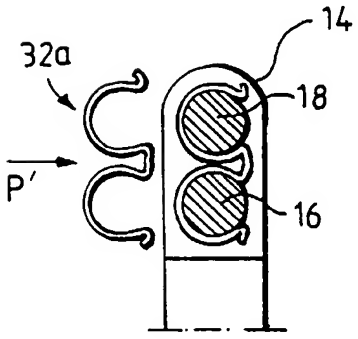


Fig.4

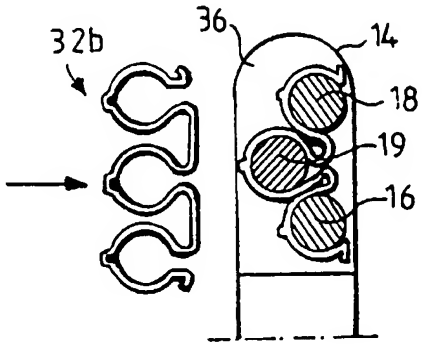


Fig.5

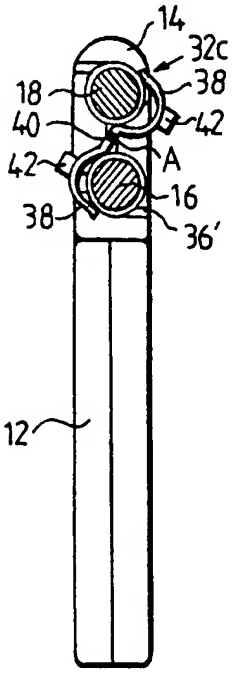


Fig.6

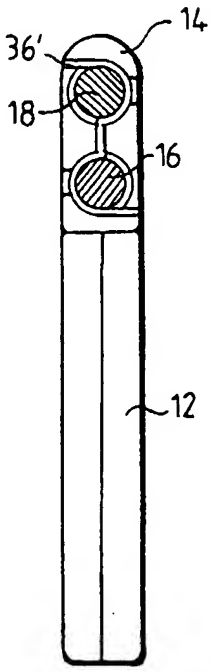


Fig.7

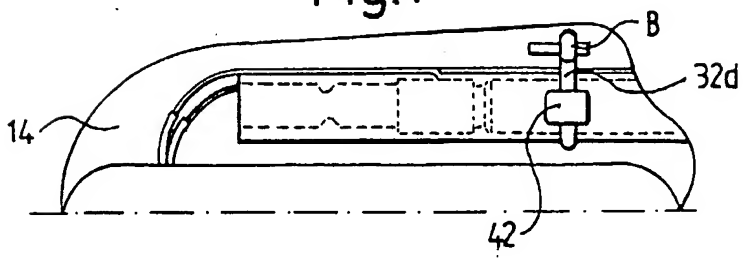


Fig.8

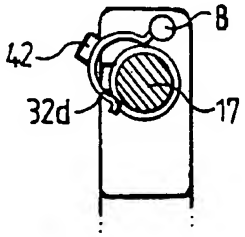
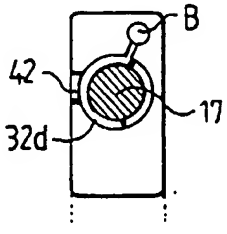


Fig.9



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EUROPEAN SEARCH REPORT

Application Number
EP 96 85 0072.8

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	US, A, 4848346 (K.F. CRAWFORD), 18 July 1989 (18.07.89) * column 3, line 28 - column 4, line 44, see the figures * --	1,11-13	A61N 1/375 H01R 13/58
A	US, A, 5261395 (F.G. OLEEN ET AL), 16 November 1993 (16.11.93) * figures 1-6, abstract * --	1	
A	US, A, 4860750 (M.L. FREY ET AL), 29 August 1989 (29.08.89) * figures 1-4, abstract * --	1	
P,X	WO, A1, 9510324 (PACESETTER, INC.), 20 April 1995 (20.04.95) * figure 1, abstract * -----	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.6)

A61B
A61N
H01R
H02G

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	12 July 1996	SKAGERSTEN THOMAS

CATEGORY OF CITED DOCUMENTS

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